International Biobank and Cohort Studies Meeting:
Developing a Harmonious Approach
Atlanta, Georgia, February 7-8, 2005

The Human Genome Epidemiology Network (HuGE Net), in collaboration with the Public Population Project in Genomics (P3G) and the National Heart, Lung and Blood Institute, convened a multidisciplinary group of experts including geneticists, epidemiologists, laboratorians, biostatisticians, lawyers and medical publishers in Atlanta. Participants represented the members of the P3G project, (including Cartagene), HuGE Net, the UK biobank, the KORA-gen biobank from Germany, the GenomEUtwin biobank project from Sweden, the National Heart, Lung and Blood Institute, the National Children's Study, the Marshfield Personalized Medicine Project, and the Kaiser Permanente Northern California biobank project.

In addition to informing each of the participants regarding the progress made in each of the nascent Biobank projects underway around the world and spurring collegial interactions, the main goal for the meeting was to discuss the possibility of producing an overall statement aimed at harmonizing the format and improving the quality of publications arising from Biobank-based genetic-epidemiologic studies. The meeting also focused on beginning work towards producing a statement similar to that produced for randomized clinical trials (the CONSORT statement) and for observational studies (STROBE). Discussion on this process centered around creating a checklist and flowchart that would clearly describe the data flow within each Biobank study, allowing for the proper interpretation and future use in systematic reviews or meta-analyses. Important attributes of such a statement would include a thorough description of (a) study objectives and a-priori hypotheses; (b) participants; (c) genotyping processes; (d) exposure measurements; (e) outcome definitions and measurements; (f) statistical analysis plan including power and sample size descriptions; (g) assessment of confounding (including population substratification and other genotypic confounding); and (h) methods for subanalyses. This statement would serve as guidelines for publication, and could also be used to help guide investigators in planning studies at the time investigators first approach Biobanks with project ideas.

Considerable discussion followed and focused on the best avenue for providing and archiving the large amounts of data that will be produced from Biobank studies, and how to make this data available for future use. Also, consideration of and substantial support was given for a proposal that Biobanks produce a design and conduct template outlining basic structure, including intellectual property guidance, human subjects protection, and information technology standards. Such a template of core elements could be used as a reference document, to which each Biobank-based study could refer at the time of initiation and publication. The participants also agreed on the need of an online knowledge base that could include a repository of information on biobanks and their tools (e.g. questionnaires; data entry management; informed consent; confidentiality; governance documents …) on the P3G website.

The meeting participants agreed to develop the following products:

1. A paper reporting on the biobank meeting and laying out the challenges and opportunities for human genome epidemiology studies in the context of biobanks. This paper would also contain extensions to STROBE statement that are specific to biobanks with examples and explanations from this field
2. Because of the overlap of biobank projects with general human genome epidemiology studies, a more general "module" on standards for presenting human genome epidemiologic data within the STROBE framework
3. A set of guidelines for documenting biobank structure, standards and procedures. It was also proposed that biobanks produce a separate statement outlining its structure, including intellectual property guidance, human subjects protection, and information technology standards. Such a report could be used as a reference document, to which each Biobank-based study could refer at the time of publication.
4. The P3G led knowledge base group will take the lead in developing online repository of tools (e.g. informed consent documents), and register of biobank studies.